REMARKS

I. STATUS OF CLAIMS

Claims 32, 34, 35, 38, 42, 43, 45-48, 50, and 59-64 are pending in this application. No amendments are presented herein.

II. EXAMINER INTERVIEW

Applicants' thank Examiner Carr for the courtesies extended to Applicants' undersigned representatives on November 17, 2009. Applicants agree with the substance of the Interview Summary dated November 17, 2009.

III. REJECTION UNDER 35 U.S.C. § 112

The Office newly rejects claims 32, 34, 35, 38, 43, 43, 45-48, 50, and 59-64 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Office Action at page 2. Specifically, the Office contends that "a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia is not present nor are working examples." *Id.* at page 4. The Office states that "[b]ased on applicants argument that the FDA has established that [ ] known compositions contain these components [that] cannot be use [sic] to [ ] administer[ ] as a pharmaceutical, experimentation would be needed to ascertain the pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia." *Id.* at page 5. Applicants respectfully disagree and traverse the rejection for the following reasons.

In an Information Disclosure Statement and accompanying Supplemental Preliminary Amendment filed March 12, 1997, Applicants identified U.S. Patent Nos. 5,502,077 (issue date March 26, 1996), 5,656,667 (issued date August 12, 1997), and 5,698,594 (issued date December 16, 1997). Those patents teach, *inter alia*, a

pharmaceutical composition comprising at least 80% by weight of EPA and DHA administered in amounts providing a daily dosage of 1 to 10 grams of fatty acids for the treatment of hypertriglyceridaemia. *See e.g.*, U.S. Patent No. 5,502,077 at Claim 1, Abstract, Col. 6, line 20 - Col. 10, line 46. Since those patents issued/published before the earliest effective filing date of the present application, they demonstrate the state of the art and subject matter known to a person of ordinary skill in the art. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). "It is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation." M.P.E.P. § 2161.04(c). Thus, the present disclosure enables a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia. Accordingly, Applicants respectfully request the withdrawal of the rejection.

IV. REJECTION UNDER 35 U.S.C. § 102

The Office maintains the rejection of claims 32, 34, 35, 38, 42, 43, 45-48, 50, and 59-64 under 35 U.S.C. § 102(b), as anticipated by EPAX Product Specifications for EPAX 4020EE or 5500EE or 6000EE or 6010EE. Office Action at page 5. The Office contends that no direction regarding dosages is provided. *Id.* As a result, the Office alleges that the EPAX product specifications "can be administered in such a way to therapeutically treat hypertriglyceridaemia." *Id.* at pages 5 and 6. The Office further contends that because a pharmaceutical use is "any use, other than food" and the EPAX compositions are described as health supplements not food, "the dosage is the same when given as a health supplement or pharmaceutical." *Id.* at page 6. Applicants

respectfully disagree and traverse the rejection for the reasons of record and for the additional reasons below.

To anticipate a claim, a single reference must teach either explicitly or inherently each and every element of the claim. M.P.E.P. § 2131. Here, the EPAX Product Specifications (i.e., EPAX 4020EE or 5500EE or 6000EE or 6010EE) fail to teach each and every element of the present claims.

For example, as articulated under the enablement rejection, a person of ordinary skill in the art would understand what "a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" encompasses. In contrast, the EPAX Product Specifications (i.e., EPAX 4020EE or 5500EE or 6000EE or 6010EE) teach amounts and percent by weight values of EPA and DHA less than "a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" encompasses.

Moreover, the EPAX Product Specifications (i.e., EPAX 4020EE or 5500EE or 6000EE or 6010EE) are directed to health supplements. The present specification, at page 21, lines 1-4, defines the term "health supplement" to "include food and food supplement to animals and/or humans, fortification of food, dietary supplement, functional (and medical) food and nutrient supplement." The presently pending claims expressly recite "wherein said pharmaceutical composition is not a health supplement." This is in contrast to the Office's interpretation of health supplements and the alleged interchangeability of health supplements and pharmaceutical compositions. Office Action at page 6. To that end, health supplements and pharmaceutical compositions are distinct, as evidenced by the present specification and claims, and the art.

For at least those reasons, the EPAX Product Specifications (i.e., EPAX 4020EE or 5500EE or 6000EE or 6010EE) fail to anticipate claims 32, 34, 35, 38, 42, 43, 45-48, 50, and 59-64 under 35 U.S.C. § 102(b). Accordingly, Applicants respectfully request the withdrawal of the rejection.

V. CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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